EXHIBIT J Application Serial No. 09/089,871

The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CARL SIDONIUS MARIA ANDELA and AUGUSTINUS BERNARDUS MARIA KLEIN HOLKENBORG

Appeal No. 2006-0201 Application No. 10/125,272

ON BRIEF

Before MILLS, GRIMES, and GREEN, <u>Administrative Patent Judges</u>.
GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of making enzyme-containing granules. The examiner has rejected the claims as anticipated by or obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. Because the examiner has not adequately explained how the cited references teach or suggest a process that meets all the limitations of the present claims, we reverse all of the rejections.

Background

"The use of various enzymes in animal, e.g. livestock, feed has become almost common practice." Specification, page 1. "Dry enzyme formulations may be added to the feed before pelleting and therefore are subjected to heat-inactivation during

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pelleting. Preferred manufacturing protocols in the feed industry involve steam pelleting where the feed is subjected to steam injection(s) prior to pelleting, a process called conditioning. . . . During this conditioning process temperatures may rise to 60-95°C.

The combined effect of high moisture content and high temperature is detrimental to most enzymes." Pages 1-2.

The specification discloses "a process for the preparation of an enzyme-containing granulate suitable for use in an animal feed, the process comprising processing an enzyme, a solid carrier, optionally additives and water . . . to obtain enzyme-containing granules, drying the granules, and coating the dried granules with polyethylene glycol." Page 3.

The specification reports that coating the granules with polyethylene glycol (PEG) "protect[s] against the formation of dust" and "provide[s] a good pelleting stability of the granule"; i.e., results in less loss of enzyme activity during pelleting. Page 4, lines 1-2 and 7-8. Moreover, granules coated with PEG dissolve twenty times faster than granules with a fat-type coating, and "[a] short dissolution time significantly improves the bioavailability of the enzyme to the animal." Page 4, lines 3-7.

Discussion

1. Claim construction

Claims 1 and 3-36 are on appeal. Claim 1 is the only independent claim and reads as follows:

- 1. A process for the preparation of an enzyme-containing granulate suitable for use in animal feed, the process comprising:
 - (a) mixing a feed enzyme, a solid carrier, water, and at least one additive in an effective amount;

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- (b) mechanically processing the mixture obtained in (a), simultaneously with or subsequently to the mixing, to obtain enzyme-containing granules;
- drying the granules; and (c)
- (d) coating the granules obtained in (c) with polyethylene glycol, wherein the polyethylene glycol has a molecular weight ranging from 6,000 to 20,000 Dalton, the granules obtained in (d) having 1) a dissolution time shorter that granules coated with oil or fat, and 2) a pelleting stability greater than uncoated granules.

The preamble of claim 1 states that the claimed process is for preparing granules "suitable for use in animal feed." "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Commc'ns Research Inc. v. Vitalink Commc'ns Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). We interpret the preamble of claim 1 to limit the potential components of the granules to those that are compatible with feeding the resulting granules to an animal. The claim however, is not limited to a method of making granules that are only suitable for use in animal feed.

The method of claim 1 comprises mixing water, a solid carrier, a feed enzyme, and "at least one additive." The specification states that "[t]he solid carrier to be used to prepare the granulate . . . is a powder which can be compacted into a granule[,] . . . preferably halving an average particle size ranging between 5 and 20 µm." Page 5. lines 1-4. "Feed enzymes include: phosphatases . . .; carbohydrases . . .; [and] proteases . . . ," among others. Specification, page 8, lines 1-9. Suitable additives

include water-soluble inorganic salts, "hydrophobic, gel-forming or slowly dissolving compounds," and trehalose. Page 6, lines 3-27.

Thus, the process of claim 1 requires mixing water, an enzyme (e.g., a phosphatase or a protease), a "powder which can be compacted into a granule," and an additive; mechanically processing the mixture to obtain granules; drying the granules and coating them with PEG having a molecular weight of 6000 to 20,000 Daltons.

Claim 1 also states that the resulting granules have "a dissolution time shorter than [that of] granules coated with oil or fat, and . . . a pelleting stability greater than uncoated granules."

2. Anticipation

The examiner rejected claims 1, 5, 7, 9, 12, 14, 15, 19, 20, 23, 31, and 34-36 under 35 U.S.C. § 102(e) as anticipated by De Lima, 1 reasoning that

[t]he patent teaches making an enzyme containing granulate suitable for use in animal feed. The patent teaches mixing a feed enzyme, a solid carrier, water and at least one additive. The patent then mechanically processes the mixture to form the granules, dries them and then coats the granulates with polyethylene glycol (PEG).

Examiner's Answer, page 5.

Appellants argue that the reference does not identically disclose the claimed process because, among other things, "whereas De[]Lima begins with a granular core particle, Appellants' invention begins with a mixture that is processed into a granule."

Appeal Brief, page 11. Appellants reason that "[t]he core in De[]Lima differs from the solid carrier in Appellants' claim 1.... De[]Lima teaches that its carrier particles

¹ De Lima et al., U.S. Patent 6,136,772, issued October 24, 2000.

preferably have relatively high physical strength. . . . In contrast, Appellants' solid carrier is a 'powder which can be compacted into a granule.'" Id.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also Gechter v. Davidson, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed. Cir. 1997) ("[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference.").

In this case, the claims require mixing an enzyme with "a powder which can be compacted into a granule," and mechanically processing the mixture to obtain granules. The process described by De Lima, on the other hand, begins with "absorbent cores" and then contacts them with an enzyme-containing liquid. See, e.g., column 2, lines 22-29: "a process for producing enzyme-containing granules from absorbent cores, the process comprising: (a) contacting absorbent cores . . . with a liquid medium containing an enzyme in dissolved and/or dispersed form." The disclosed process therefore does not involve mixing an enzyme with a solid carrier as defined in the instant specification — "a powder which can be compacted into a granule" — and processing to produce granules.

The examiner responded to Appellants' argument by pointing to De Lima's working examples: "De Lima very clearly teaches that the compositions are **formulated** as granulates not starting with a granulate. Appellant does the same thing as De Lima, appellant also formulates a granulate by mixing the enzyme, carrier, water and an

additive together to form the granulate which is exactly what De Lima also teaches, see examples of De Lima." Examiner's Answer, page 11.

We have reviewed the working examples described by De Lima and find none that include combining a powder that can be compacted into a granule with an enzyme and processing to produce granules. On the contrary, De Lima's examples begin with granular starch cores (see, e.g., column 24, lines 15 and 65). The examiner has pointed to no specific example in De Lima that begins with a powder that is combined with water, an enzyme, and an additive, and processed into granules.

Because the process taught by De Lima does not meet all the limitations of claim 1, we reverse the rejection under 35 U.S.C. § 102(e).

3. Obviousness based on De Lima and Yamada

The examiner rejected claims 1 and 3-36 under 35 U.S.C. § 103 on the basis that the claimed process would have been obvious to those of ordinary skill in the art based on the disclosures of De Lima and Yamada.² The examiner characterized De Lima as teaching the process defined in claim 1, although he acknowledged that De Lima "does not teach using the specific amounts of components, such as trehalose or zinc sulfate as the additive, etc." Examiner's Answer, page 5.

The examiner characterized Yamada as "teach[ing] that granular solid enzyme preparations are stabilized by using trehalose and zinc sulfate," and concluded that "[i]t would have been obvious to one of ordinary skill in the art to use trehalose or zinc sulfate instead of PVA as the additive in the enzyme granulate of De Lima since

² Yamada et al., EP 501375 A1, published September 2, 1992

[Yamada] teaches that trehalose and zinc sulfate are both good enzyme stabilizers." ld., page 6.

Appellants argue that "as . . . discussed above, the De[]Lima and [Yamada] processes are quite different from Appellants' process. The granules are formed in De[]Lima by spraying and mixing an aqueous enzyme onto a preformed core. The granules are formed in [Yamada] by mixing a disaccharide and an enzyme and spray drying." Appeal Brief, page 13.

We agree with Appellants that Yamada does not remedy the deficiency of De Lima. Specifically, the examiner has not adequately explained why Yamada's disclosure – stabilizing an enzyme by mixing it with a disaccharide before spray-drying – would have led a person of ordinary skill in the art to modify De Lima's disclosed process – coating pre-formed cores with an enzyme-containing liquid – in such a way as to result in the process defined by claim 1.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a <u>prima facie</u> case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." <u>In re Rijckaert</u>, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Because the examiner has not adequately explained why the cited references would have suggested the process of claim 1 to a person of ordinary skill in the art, he has not established a <u>prima facie</u> case of obviousness. We therefore reverse the rejection under 35 U.S.C. § 103.

4. Other obviousness rejections

The examiner also rejected claims 1 and 3-36 under 35 U.S.C. § 103, based on the following combinations of references:

- Barendse³ or Harz, 4 combined with De Lima and Yamada;
- Olsen⁵ or Bisgard-Frantzen, ⁶ combined with Yamada; and
- WO 98/54980⁷ or WO 98/55599, ⁸ combined with De Lima and Yamada.

The examiner characterized the additional references as follows:

- "Barendse and Harz each teach an enzyme containing granulate" (Examiner's Answer, page 7);
- "Olsen and Bisgard[-Frantzen] each teach making the claimed enzyme containing granulate since they teach enzymes mixed with water, a carrier and an additive" (id., page 8); and
- "The WO's each teach making the claimed enzyme containing granulate" (id., page 9).

We have reviewed the cited references but neither the examiner's explanation of the rejection nor our review of the reference has revealed any disclosure that would have suggested a process meeting all the limitations of the method of instant claim 1.

None of the additional references make up for the deficiencies of De Lima and Yamada, discussed above. We therefore reverse the rejections based on Barendse or Harz.

³ Barendse et al., U.S. Patent 5,827,709, issued October 27, 1998

⁴ Harz et al., U.S. Patent 5,972,669, issued October 26, 1999

⁵ Olsen et al., U.S. Patent 5,856,451, issued January 5, 1999

⁶ Bisgard-Frantzen et al., U.S. Patent 6,106,828, issued August 22, 2000

⁷ Barendse et al., WO 98/54980, published December 10, 1998

⁸ Barendse et al., WO 98/55599, published December 10, 1998

combined with De Lima and Yamada; Olsen or Bisgard-Frantzen, combined with Yamada; and WO 98/54980 or WO 98/55599, combined with De Lima and Yamada.

Summary

The examiner has not adequately shown that De Lima disclosed, or that the cited references collectively would have suggested, the process defined by claim 1 on appeal. We therefore reverse all of the rejections.

REVERSED

Demetra J. Mills Administrative Patent Judge)))
Eric Grimes Administrative Patent Judge)) BOARD OF PATENT
)) APPEALS AND
)) INTERFERENCES
Lora M. Green Administrative Patent Judge)))

EG/jlb